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Integration of filgrastim into chemoradiation for limited small cell lung cancer: a Phase I study.

Glisson B, Komaki R, Lee JS, Shin DM, Fossella F, Murphy WK, Kurie Perez-Soler R, Schea R, Vadhan-Raj S.

Department of Thoracic/Head and Neck Medical Oncology, The University of Texas M. D. Anderson Cancer Center, Houston 77030, USA.

PURPOSE: Recent studies document the value of early combined modality therapy in small cell lung cancer, but also indicate that early thoracic radiation adds to myelosuppression and can complicate further chemotherapy. Other studies indicate that simultaneous use of growth factors with thoracic radiation may be deleterious. However, temporal separation of growth factor use from cytotoxic therapy may allow dose intensity to be maintained/enhanced during combined modality treatment. We sought to integrate filgrastim into a novel chemoradiation regimen for patients with limited small cell lung cancer using an approach that separates growth factor administration from both chemotherapy and thoracic radiation.

METHODS AND MATERIALS: Twenty-seven patients with limited disease stage small cell lung cancer were enrolled in a Phase I trial of cisplatin, ifosfamide/mesna, oral etoposide, and thoracic radiation (1.5 Gy b.i.d. x 30 fractions days 1-19 cycle 1) +/- filgrastim (5 microg/kg/day). Filgrastim was given on days 20-25 of cycle 1 after completion of radiation and following completion of oral etoposide in subsequent cycles. The primary end point was determination of maximum tolerated dose (MTD) of chemotherapy. Serial cohorts were treated with and without filgrastim. **RESULTS:** Because of dose-limiting thrombocytopenia, primarily, and nonhematologic toxicity, the MTDs with and without filgrastim were identical (cisplatin 20 mg/m² i.v. and ifosfamide 1200 mg/m² i.v., both days 1-3, and etoposide 40 mg/m² p.o. days 1-14). Filgrastim use shortened the duration of neutropenia at the MTD (median 4 vs. 7 days), but was not associated with a reduction in febrile neutropenia. Although growth factor administration did not allow dose escalation of this regimen, it did allow chemotherapy doses to be maintained at the MTD more frequently through four cycles of therapy. In the evaluable patients, the overall response rate was 100% (71% partial and 29% complete). **CONCLUSIONS:** Despite careful attention to the timing of growth factor with chemoradiation, the administration of filgrastim with this regimen did not allow dose escalation. As in many other recent studies of hematopoietic growth factors, filgrastim did not allow dose escalation.

factors given prophylactically with chemotherapy, the duration of neutropenia the MTD was shortened and the need for dose reduction throughout treatment reduced in patients receiving filgrastim at the MTD.

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